

CLAIMS:

1. A method for selecting a medicament for a medical procedure for treatment or prevention of a disease or disorder of a mucosa, the method comprising:

5 (a) providing a medicament comprising charged lipid assemblies loaded with an active ingredient, said charged lipid assemblies being selected from positively charged lipid assemblies and negatively charged lipid assemblies;

(b) determining said medical procedure;

10 (c) selecting the medicament, wherein

i) for preventing a disease or disorder of a mucosa membrane, said medicament comprises positively charged lipid assemblies;

ii) for treating a disease or disorder of a mucosa membrane, said medicament comprises negatively charged lipid assemblies.

15 2. The method of Claim 1, wherein for treatment of a disease or disorder of a mucosa, the medicament selected comprises negatively charged lipid assemblies loaded with an active ingredient.

3. The method of Claim 1 or 2, wherein said mucosa is the gastrointestinal mucosa.

20 4. The method of Claim 3, wherein said mucosa is selected from intestinal mucosa, small bowel mucosa, large bowel mucosa or the mucosa in the rectum.

5. The method of Claim 4, wherein said mucosa is the intestinal mucosa.

6. The method of any one of Claims 2 to 5, wherein said lipid assemblies comprise one or more anionic lipids selected from 1,2-distearoyl-*sn*-glycero-3-

25 [phospho-*rac*-(1-glycerol)] (DSPG), hydrogenated soy phosphoglycerol (HSPG).

7. The method of Claim 1, wherein for prevention of a disease or disorder of a mucosa, the medicament selected comprises positively charged lipid assemblies loaded with an active ingredient.

8. The method of Claim 1 or 7, wherein said mucosa is the gastrointestinal mucosa.

9. The method of Claim 8, wherein said mucosa is selected from intestinal mucosa, small bowel mucosa, large bowel mucosa or the mucosa in the rectum.

5 10. The method of Claim 9, wherein said mucosa is the intestinal mucosa.

11. The method of any one of Claims 7 to 10, wherein said lipid assemblies comprise one or more cationic lipids selected from 1,2-dioleyloxy-3-(trimethylamino) propane (DOTAP); cholesterol, dioctadecylmethylammonium bromide (DODAB), N-[1-(2,3,-ditetradecyloxy)propyl]-N,N-dimethyl-N-10 hydroxyethylammonium bromide (DMRIE); N-[1-(2,3,-dioleyloxy)propyl]-N,N-dimethyl-N-hydroxy ethylammonium bromide (DORIE); N-[1-(2,3-dioleyloxy)propyl]-N,N,N-trimethylammonium chloride (DOTMA); 3 β [N-(N',N'-dimethylaminoethane) carbamoly] cholesterol (DC-Chol); dimethyldioctadecylammonium (DDAB), N,N-dimethyl- 2,3-bis[(1-oxo-9-15 octadecenyl)oxy]-1-propanaminium, (DOSPA), N-(2-hydroxyethyl)-N,N-dimethyl-2,3-bis(tetradecyloxy)-1-propanaminium, and N-palmitoyl D-erythro sphingosyl-1-carbamoyl spermine (CCS).

12. The method of any one of Claims 1 to 11, wherein said disease or disorder is associated with a condition selected from inflammation, long term or short term 20 oxidative stress, motility disorder or malignant processes.

13. The method of Claim 12, wherein said disease or disorder is associated with inflammation, and said medicament comprises an active ingredient is an agent effective in inhibiting inflammatory responses.

14. The method of Claim 12, wherein said disease or disorder is associated 25 with oxidative stress, and said medicament comprises as an active ingredient one or more anti-oxidants.

15. The method of any one of Claims 3 to 14; wherein said disease or disorder is selected from ulcerative colitis, Crohn's disease, irritable bowel syndrome, colon carcinoma and familial adenomatous polyposis (FAP).

16. The method of any one of Claims 1 to 15, wherein said medicament is in a form suitable for oral or nasal administration.

17. A kit for executing a medical procedure, the medical procedure selected from treatment and prevention of a disease or disorder of a mucosa, the kit 5 comprising:

- (a) a first package comprising positively charged lipid assemblies loaded with an active ingredient;
- (b) a second package comprising negatively charged lipid assemblies loaded with an active ingredient;
- 10 (c) instructions for use of said first and second package, for executing the medical procedure, said instructions defining:
 - i) steps for use of said first package for preventing a disease or disorder of a mucosa;
 - 15 ii) steps for use of said second package for treating a disease or disorder of a mucosa;
 - iii) steps for use of said first and said second package in combination for treatment and prevention of a disease or disorder of a mucosa.

18. The kit of Claim 17, comprising a third package comprising a 20 physiologically acceptable carrier suitable for oral or nasal administration of said lipid assemblies.

19. The kit of Claim 18, wherein said third package comprises a physiologically acceptable carrier suitable for oral administration.

20. The kit of any one of Claims 17 to 19, wherein the negatively charged 25 lipid assemblies comprise one or more anionic lipids selected from 1,2-distearoyl-*sn*-glycero-3-[phospho-*rac*-(1-glycerol)] (DSPG), hydrogenated soy phosphoglycerol (HSPG).

21. The kit of any one of Claims 17 to 19, wherein said positively charged lipid assemblies comprise one or more cationic lipids selected from 1,2-dioleyloxy-3-(trimethylamino) propane (DOTAP); cholesterol,

dioctadecylmethylammonium bromide (DODAB), N-[1-(2,3,-ditetradecyloxy)propyl]-N,N-dimethyl-N-hydroxyethylammonium bromide (DMRIE); N-[1-(2,3,-dioleyloxy)propyl]-N,N-dimethyl-N-hydroxyethylammonium bromide (DORIE); N-[1-(2,3-dioleyloxy) propyl]-N,N,N-5 trimethylammonium chloride (DOTMA); 3 β [N-(N',N'-dimethylaminoethane) carbamoly] cholesterol (DC-Chol); and dimethyldioctadecylammonium (DDAB), N,N-dimethyl- 2,3-bis[(1-oxo-9-octadecenyl)oxy]-1-propanaminium, (DOSPA), N-(2-hydroxyethyl)-N,N-dimethyl-2,3-bis(tetradecyloxy)-1-propanaminium), and N-palmitoyl D-erythro sphingosyl-1-carbamoyl spermine (CCS).

10 22. The kit of any one of Claims 17 to 21, wherein said mucosa is the gastrointestinal mucosa.

23. The kit of Claim 22, wherein said mucosa is selected from intestinal mucosa, small bowel mucosa, large bowel mucosa or the mucosa in the rectum.

24. The kit of Claim 23, wherein said mucosa is the intestinal mucosa.

15 25. The kit of any one of Claims 17 to 24, wherein said disease or disorder is associated with a condition selected from inflammation, long term or short term oxidative stress, motility disorder or malignant processes.

26. The kit of Claim 25, wherein said disease or disorder is associated with inflammation, and said medicament comprises an active ingredient is an agent 20 effective in inhibiting inflammatory responses.

27. The kit of Claim 25, wherein said disease or disorder is associated with oxidative stress, and said medicament comprises as an active ingredient one or more anti-oxidants.

28. The kit of any one of Claims 17 to 27, wherein said disease or disorder is 25 selected from ulcerative colitis, Crohn's disease, irritable bowel syndrome, colon carcinoma and familial adenomatous polyposis.

29. A method for performing a medical procedure comprising treatment or prevention of a disease or disorder of a gastrointestinal mucosa, the method comprises providing a subject in need of said medical procedure with an amount 30 of a medicament comprising charged lipid assemblies loaded with an active

ingredient, the amount being effective to achieve a therapeutic effect on said GI mucosa.

30. The method of Claim 29, for the prevention of a disease or disorder of the GI mucosa, the method comprising providing said subject a medicament 5 comprising positively charged lipid assemblies loaded with an active ingredient.

31. The method of Claim 29, for the treatment of a disease or disorder of the GI mucosa, the method comprising providing said subject a medicament comprising negatively charged lipid assemblies loaded with an active ingredient.

32. The method of any one of Claims 29 to 31, wherein said medicament is 10 in a dosage form suitable for oral or nasal administration.

33. The method of claim 32, wherein said medicament is in a dosage form suitable for oral administration.

34. The method of any one of Claims 29 to 33, wherein said GI mucosa is selected from intestinal mucosa, small bowel mucosa, large bowel mucosa or the 15 mucosa in the rectum.

35. The method of Claim 34, wherein said mucosa is the intestinal mucosa.

36. The method of any one of Claims 29 to 35, wherein said lipid assemblies comprise one or more anionic lipids selected from 1,2-distearoyl-*sn*-glycero-3-[phospho-*rac*-(1-glycerol)] (DSPG), hydrogenated soy phosphoglycerol.

20 37. The method of any one of Claims 29 to 35, wherein said lipid assemblies comprise one or more cationic lipids selected from 1,2-dioleyloxy-3-(trimethylamino) propane (DOTAP); cholesterol, dioctadecylmethylammonium bromide (DODAB), N-[1-(2,3,-ditetradecyloxy)propyl]-N,N-dimethyl-N-hydroxyethylammonium bromide (DMRIE); N-[1-(2,3,-dioleyloxy)propyl]-N,N-25 dimethyl-N-hydroxy ethylammonium bromide (DORIE); N-[1-(2,3-dioleyloxy)propyl]-N,N,N-trimethylammonium chloride (DOTMA); 3 β [N-(N',N'-dimethylaminoethane) carbamoly] cholesterol (DC-Chol); and dimethyldioctadecylammonium (DDAB), N,N-dimethyl- 2,3-bis[(1-oxo-9-octadecenyl)oxy]-1-propanaminium, (DOSPA), N-(2-hydroxyethyl)-N,N-

dimethyl-2,3-bis(tetradecyloxy)-1-propanaminium), and N-palmitoyl D-erythro sphingosyl-1-carbamoyl spermine (CCS).

38. The method of any one of Claims 29 to 38, wherein said disease or disorder is associated with a condition selected from inflammation, long term or 5 short term oxidative stress, motility disorder or malignant processes.

39. The method of Claim 38, wherein said disease or disorder is associated with inflammation, and said medicament comprises an active ingredient is an agent effective in inhibiting inflammatory responses.

40. The method of Claim 38, wherein said disease or disorder is associated 10 with oxidative stress, and said medicament comprises as an active ingredient one or more anti-oxidants.

41. The method of any one of Claims 29 to 40, wherein said disease or disorder is selected from ulcerative colitis, Crohn's disease, irritable bowel syndrome, colon carcinoma and familial adenomatous polyposis.

15 42. Use of charged lipid assemblies for the preparation of a medicament for performing a medical procedure comprising prevention or treatment of a disease or disorder of the GI mucosa, wherein for preventing a disease or disorder of the mucosa, positively charged lipid assemblies are used while for treating a disease or disorder of a mucosa negatively charged mucosa are use.

20 43. The use of Claim 42, in combination with an active ingredient.

44. The use of Claim 42 or 43, wherein said mucosa is selected from intestinal mucosa, small bowel mucosa, large bowel mucosa or the mucosa in the rectum.

45. The use of Claim 44, wherein said mucosa is the intestinal mucosa.

25 46. The use of any one of Claims 42 to 45, wherein said medicament is for treating a disease or disorder of the mucosa and said lipid assemblies comprise one or more anionic lipids selected from 1,2-distearoyl-*sn*-glycero-3-[phospho-rac-(1-glycerol)] (DSPG), hydrogenated soy phosphoglycerol (HSPG).

47. The use of any one of Claims 42 to 45, wherein said medicament is for 30 the prevention of a disease or disorder of the mucosa and said lipid assemblies

comprise one or more cationic lipids selected from 1,2-dioleyloxy-3-(trimethylamino) propane (DOTAP); cholesterol, dioctadecylmethylammonium bromide (DODAB), N-[1-(2,3,-ditetradecyloxy)propyl]-N,N-dimethyl-N-hydroxyethylammonium bromide (DMRIE); N-[1-(2,3,-dioleyloxy)propyl]-N,N-5 dimethyl-N-hydroxy ethylammonium bromide (DORIE); N-[1-(2,3-dioleyloxy)propyl]-N,N,N-trimethylammonium chloride (DOTMA); 3 β [N-(N',N'-dimethylaminoethane) carbamoly] cholesterol (DC-Chol); and dimethyldioctadecylammonium (DDAB), N,N-dimethyl- 2,3-bis[(1-oxo-9-octadecenyl)oxy]-1-propanaminium, (DOSPA), N-(2-hydroxyethyl)-N,N-10 dimethyl-2,3-bis(tetradecyloxy)-1-propanaminium, and N-palmitoyl D-erythro sphingosyl-1-carbamoyl spermine (CCS)..

48. The use of any one of Claims 42 to 47, for the preparation of a medicament for the treatment or prevention of a disease or disorder associated with a condition selected from inflammation, long term or short term oxidative stress, motility 15 disorder, or malignant processes.

49. The use of Claim 48, wherein said condition is inflammation, and said active ingredient is an agent effective in inhibiting inflammatory responses.

50. The use of Claim 48, wherein said disease or disorder is associated with oxidative stress, and said active ingredient one or more anti-oxidants.

20 51. The use of any one of Claims 42 to 50, for the preparation of a medicament for the treatment or prevention of a disease or disorder is selected from ulcerative colitis, Crohn's disease, irritable bowel syndrome, colon carcinoma and familial adenomatous polyposis.

52. A medicament for achieving a therapeutic effect comprising prevention 25 or treatment of a disease or disorder of the GI mucosa, said medicament comprises charged lipid assemblies loaded with an amount of an active ingredient, the amount of the active ingredient being effective to achieve said therapeutic effect.

53. The medicament of Claim 52, wherein said mucosa is selected from intestinal mucosa, small bowel mucosa, large bowel mucosa or the mucosa in the rectum.

54. The medicament of Claim 53, wherein said mucosa is the intestinal mucosa.

55. The medicament of any one of Claims 52 to 54, wherein said lipid assemblies comprise one or more anionic lipids selected from 1,2-distearoyl-*sn*-glycero-3-[phospho-*rac*-(1-glycerol)] (DSPG), hydrogenated soy phosphoglycerol (HSPG).

10 56. The medicament of any one of Claims 60 to 62, wherein said lipid assemblies comprise one or more cationic lipids selected from 1,2-dioleyloxy-3-(trimethylamino) propane (DOTAP); cholesterol, dioctadecylmethylammonium bromide (DODAB), N-[1-(2,3,-ditetradecyloxy)propyl]-N,N-dimethyl-N-hydroxyethylammonium bromide (DMRIE); N-[1-(2,3,-dioleyloxy)propyl]-N,N-15 dimethyl-N-hydroxy ethylammonium bromide (DORIE); N-[1-(2,3-dioleyloxy)propyl]-N,N,N-trimethylammonium chloride (DOTMA); 3 β [N-(N',N'-dimethylaminoethane) carbamoly] cholesterol (DC-Chol); and dimethyldioctadecylammonium (DDAB), N,N-dimethyl- 2,3-bis[(1-oxo-9-octadecenyl)oxy]-1-propanaminium, (DOSPA), N-(2-hydroxyethyl)-N,N-20 dimethyl-2,3-bis(tetradecyloxy)-1-propanaminium, and N-palmitoyl D-erythro sphingosyl-1-carbamoyl spermine (CCS).

57. The medicament of any one of Claims 52 to 56, for the treatment of a disease or disorder associated with a condition selected from inflammation, long term or short term oxidative stress, motility disorder or malignant processes.

25 58. The medicament of Claim 57, wherein said disease or disorder is associated with inflammation, and said active ingredient is an agent effective in inhibiting inflammatory responses.

59. The medicament of Claim 57, wherein said disease or disorder is associated with oxidative stress, and said active ingredient one or more anti-30 oxidants.

60. The medicament of any one of Claims 52 to 59, for the treatment of a disease or disorder is selected from ulcerative colitis, Crohn's disease, irritable bowel syndrome, colon carcinoma and familial adenomatous polyposis.

61. The medicament of any one of Claims 52 to 60, in a dosage form suitable
5 for oral or nasal administration.